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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,185	06/17/2002	Pascual Perez	34934-PCT-USA 072667.0180	2915
21003	7590	01/21/2005	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			ROBINSON, KEITH O NEAL	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/048,185

Applicant(s)

PEREZ ET AL.

Examiner

Keith O. Robinson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-8,10,12,14,15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,10,12,14,15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendments to the specification, the cancellation of claims 4, 9, 11, and 16, without prejudice, filed October 25, 2004, have been received and entered in full.

Claims 1-3, 5-6, 8, 10, 12, 15, and new claim 17 are pending.

Response to Arguments

The objections to the specification and claim 16 are withdrawn in light of the amendments. The deposit rejection is withdrawn in view of Applicant's arguments that the claims are not limited to specific individual genotypes. Submission of such claims in the future would result in the reinstatement of the deposit rejection as applied to those claims.

The indefiniteness rejections are withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 112, first paragraph

Claims 1-3, 5-6, 8, 10, 12, 15, and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to

make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office Action mailed June 25, 2004, pages 3-9, as applied to claims 1-12 and 14-16. Applicant's arguments filed October 25, 2004 have been fully considered but they are not persuasive.

Applicant argues that the specification teaches that lines other than A188, including Hi-II lines as disclosed in WO 98/32326, can be used for transformation.

This is not persuasive. The mentioning of Hi-II lines in the WO 98/32326 protocol which is cited at page 22 of the instant specification does not provide evidence that other lines can be used in the invention as claimed, only that there are other lines that may be suitable for transformation; thus the Applicant has not shown that these lines will in fact work in the claimed invention. Furthermore, Hi-II is a direct descendant of A188. The only line that is described in the specification is A188. Furthermore, this is a maize line and the specification does not show that this line can be used with all crop plants, vegetables, and flowers as claimed in claim 6. In fact, the specification does not show that even all maize plants can be used in the invention as claimed. Furthermore, the Examiner has provided evidence that transformability is genotype-dependent. Therefore, it would require undue experimentation by one skilled in the art to test every crop plant, vegetable, flower, or even every maize plant with every line that may be suitable for transformation. Applicant's assertions to the contrary are insufficient to rebut the Examiner's evidence of unpredictability.

Applicant argues that methods for analyzing and comparing genomes of transformed plants are known in the art.

This is not persuasive. Though there are methods for analyzing and comparing genomes of transformed plants, the Applicant only discloses the use of RFLP and has not shown that all methods for analyzing and comparing genomes of transformed plants will work with the invention as claimed. The specification only shows the use of RFLP with maize. There are no other methods disclosed for analyzing all crop plants, vegetables, and flowers. Examiner respectfully directs Applicant to the Staub et al reference on page 8, first paragraph, of the Office Action mailed June 25, 2004 where it states that marker systems differ in their use across populations, species, and genera and their efficiency in the detection of polymorphisms. Applicant has shown that the method for analyzing by use of RFLP and comparing maize genomes, but has not shown that all known methods of analyzing nor has Applicant shown the comparison of all genomes from all crop plants, vegetables, and flowers, only maize has been disclosed. Applicant asserts that "To adapt the exemplified techniques for a specific type of plant or genome is only routine work, as the level of skill in this art is relatively high"; however, since the Applicant has not demonstrated that the claimed invention can be used with every method of analyzing and comparing every genome (only RFLP and maize have been disclosed) it would require undue experimentation by one skilled in the art. Applicant's mere assertions are insufficient to overcome the evidence submitted by the Examiner.

Applicant argues that any line of interest would be in accordance with the claimed methods.

This is not persuasive. As stated above, the specification only provides evidence of the use of maize with A188 as a parent. There is no disclosure provided in the specification for all crop plants, vegetables, and flowers nor is there any evidence of lines suitable for transformation for all crop plants, vegetables, and flowers. Examiner disagrees with Applicant's assertion that the "examples" on page 2, lines 4-14 of the specification provide examples of elite lines that can be considered as "lines of interest". Furthermore, these "examples" are not disclosed in the specification, so one of ordinary skill would not know how use such plant lines in the context of the invention.

Applicant argues that "one of ordinary skill in the art, even without resorting to a dictionary to find their ordinary meaning, would fully appreciate what is meant by..." the terms "crop plants, vegetables, and flowers" (see page 12, lines 3-6 of Applicant's Remarks).

This is not persuasive. The rejection is not an indefiniteness rejection based on the definition of the terms; it is an enablement rejection based on inoperability of claim scope. The rejection is due to the fact that the specification does not provide any evidence of any crop plants (with the exception of maize), vegetables, and flowers used in the invention as claimed. The Applicant has not shown the invention as claimed can be used with any crop plant, vegetable, or flower. The specification does not disclose any lines suitable for transformation for any crop plant (with the exception of maize), vegetable, or flower. The specification does not provide any evidence that the A188 maize line can be used with any crop plant (other than maize), vegetable, or flower.

Applicant argues that examples of proteins that confer agronomic properties and/or properties of resistance to disease are well described in the specification on pages 11-14.

This is not persuasive. Though the specification does list examples of proteins that may confer agronomic properties and/or properties of resistance to disease, it does not provide any evidence of any of these genes encoding any of the proteins being used in the invention as claimed; therefore, undue experimentation would be required for one skilled in the art to determine which, if any, of these proteins could be used in the invention as claimed.

Applicant argues that commercial elite lines are widely known and used in the art.

This is not persuasive. Examiner acknowledges that commercial elite lines are widely known and used in the art; however, the claim reads on any commercial elite line and the specification does not give any evidence of all possible commercial elite lines from all possible plants being used in the instant invention.

Applicant argues that the invention is generic and the individual steps of the claimed methods are known in the art, and thus enabled for any plant as the genus is the plants and maize is an exemplified member of this genus.

This is not persuasive. Applicant wrongly makes the assumption that all plants are similar and that because the claimed invention can be used with maize that any plant can be used by the claimed invention. It is known in the art that plants of different species will vary in their genotypic composition and that even within a species there is

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genotypic variation. It is also well known in the art that transformation is genotype specific; therefore, all plants, i.e. crop plants, vegetables, and flowers will have different genotypic compositions from that of maize; thus undue experimentation would be required for one skilled in the art to determine which, if any, of the countless number of plants in the world would work in the invention as claimed. The specification only discloses the use of maize plants. Applicant's mere assertions are insufficient to overcome the evidence provided by the Examiner.

Applicant also argues that the use of Welsh et al, a document approximately a decade old is improper. In response to Applicant's argument based upon the age of the reference, contentions that the reference is old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

Applicant argues that Staub et al is taken out of context.

Examiner respectfully disagrees. The fact that Staub et al disclose marker systems does not enable the invention as claimed. While Staub et al teach the existence of various marker systems, they also teach the unpredictability inherent in applying any marker system to a wide variety of genotypes, as discussed previously. The specification has not shown that all marker systems can work with transformants from a cross by A188 and another maize plant. The specification only shows the use of the RFLP marker system; therefore, undue experimentation would be required for one

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skilled in the art to determine which marker system would be best suited for the invention as claimed.

Claims 1-3, 5-6, 8, 10, 12, 15, and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, as stated on pages 10-12 of the last Office Action for claims 1-12 and 14-16.

Applicant argues that "The invention is described as soon as the steps of the method are well enunciated" (see page 17, line 21 of Applicant's Remarks).

This is not persuasive. The specification only draws references from work done by others, for example see pages 11-23 and pages 26-40 and does not describe the invention in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicant argues that "The invention is described as soon as the steps of the method are well enunciated"; however, the steps of the claimed invention are not "well enunciated" in the specification. Applicant simply refers the reader to references that can be used in the claimed invention. The "generic method" has only been shown to work with maize plants and not all crop plants, vegetables, and flowers.

Furthermore, the genetic makeup of the claimed isotransgenic lines of a variety of plant species and genotypes, is not described in any way, contrary to the requirements of Lilly.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ragot et al (1994), as stated in the last Office Action for claims 11-12 and 16.

Applicant's arguments, filed October 25, 2004, have been fully considered but they are not persuasive.

Applicant argues that Ragot does not describe any isotransgenic line wherein said isotransgenic line only differs from a line of interest by the presence of the T-DNA containing the transgene. There is no evidence in the specification of any isotransgenic maize line that has no remaining DNA from the line suited for transformation. The specification only gives possible results, see page 42, line 9 to page 45, line 10 that may occur depending on a particular option. Furthermore, step (e) of the amended claim 1 states that backcrossing and selection should be repeated "until the said

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isotransgenic line is produced” and step (d) of the original claims states “backcross until the isotransgenic line is produced”. Neither the claims (original or amended) nor the specification disclose how many backcrosses that may construe. Therefore, theoretically, Ragot’s method will produce an isotransgenic line that is free from Lancaster genomic sequences.

Furthermore, the claims are essentially drawn to transgenic commercially elite corn plants. Even if the prior art fails to teach a direct comparison of the transgenic plants with their non-transformed starting materials, the resultant transgenic plants are indistinguishable from the claimed plants. See Best and Thorpe cited previously.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-8, 10, 12, 14-15, and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ishida et al (1996), in view of Does et al (1991), Hie et al (1994), Armstrong et al (1992), and Ragot et al (1994), as stated for claims 1-12 and 14-16 on pages 15-18 of the last Office Action.

Applicant’s arguments filed October 25, 2004 have been fully considered but they are not persuasive.

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In response to applicant's argument that the art, collectively, does not teach the invention as claimed because none of the cited documents teaches or suggests that a selection of hybrid primary transformants, in which the T-DNA has integrated only the genome of the parental line of interest, must be performed after transformation and before starting the backcross, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, the Applicant has stated "the claimed methods for producing isotransgenic lines require transforming a suitable line, selecting appropriate transformants, and performing backcrosses with a line of interest", see page 17 of the Response, lines 4-6; that "the present invention is directed to obtaining isotransgenic lines by combining multiple steps ... each step being known in the art", see page 17 of the Response, lines 18-21; and finally, that "the nature of the claimed invention is a combination of known methods", see page 18 of the Response, line 6. Therefore, it

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would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the references as suggested in the Office Action mailed June 25, 2004, see pages 15-18, per Applicant's admissions.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is

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571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

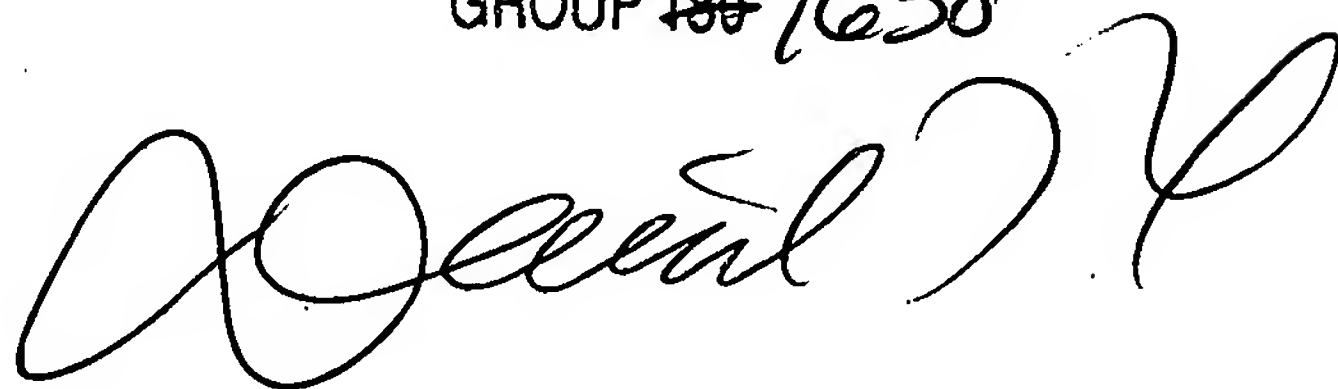
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, Ph.D. can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 13, 2005

KOR

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over the printed name and title.